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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,643

06/06/2005

Ian Hampson

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27496

7590

03/08/2007

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EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/506,643

Applicant(s)

HAMPSON ET AL.

Examiner

Stuart W. Snyder

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-21, as amended on 3 September 2004, are subject of examination.

Specification

2. The disclosure is objected to because of the following informalities: The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Screening Method for Viral Oncoprotein Binding Cellular Proteins.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "highly complex pattern of gene expression" and "high capacity for proliferation" in claim 4 are relative terms, which renders the claim indefinite. The terms "highly complex pattern of gene expression" and "high capacity for proliferation" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. All mammalian cells have "highly complex pattern of gene expression" and "high capacity for

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proliferation" as evidenced by the differentiation from stem cells and susceptibility to cancer.

4. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "according to claim 12, wherein the validation step". There is insufficient antecedent basis for this limitation in the claim. Claim 12 recites "validation phase" but not "validation step".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Berezutskaya and Bagchi. Claims 1-7 and 10-13 are drawn to methods of identifying cellular proteins that interact with known viral oncoproteins; viral oncoproteins are allowed contact with proteins and those that bind or otherwise interact with the viral oncoproteins are identified, then the identified proteins are further allowed contact with other known viral oncoproteins. Further limitations include practicing the method with a plurality of potential viral oncoprotein-interacting protein candidates, certain sources for the protein pool, certain known viral oncoproteins, derivation of candidate interacting proteins from cDNA libraries, identification of the protein sequence from the cDNA clones, and inclusion of a validation phase. Berezutskaya and Bagchi teach the identification of a cellular protein derived from a human placental cDNA library that interacted with HPV16 E7 but not E6 using a yeast two-hybrid assay. Specificity of interaction was demonstrated by binding assays using E7 and E7-derived mutants using ³⁵S-labeled proteins and observing enhanced ATPase activity of the identified protein. Thus Berezutskaya and Bagchi teach all the limitations of

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claims 1-7 and 10-13; Berezutskaya and Bagchi clearly anticipated the instantly claimed invention of claims 1-7 and 10-13.

8. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Rapp and Chen. Claims 1-15 are drawn to a method of discovering/identifying proteins that interact with HPV E6 and HTLV-I tax proteins; validation of the interaction includes analysis of transformed or tumor cell-lines for variants of the identified proteins associated with the tumorigenicity. Rapp and Chen teaches the association of HPV E6 and HTLV-I tax with hDLG protein and mutational analysis in fibroblastic cell lines to discover correlation of the presence of either or both proteins with transformation. Thus Rapp and Chen teach all the limitations of claims 1-15 and were clearly anticipated by Rapp and Chen.

Claim Rejections - 35 USC § 103The following is a quotation of 35 U.S.C. 103(a)

which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapp and Chen as applied to claims 1-15 above, and further in view of Reddy, *et al.* and Gachon, *et al.* The limitations of claims 1-15 are outlined above; Claim 16 further limits the method of claim 1 by using the cellular protein identified by the method of claim 1 as probe for discovery of other cellular proteins involved in the pathway of carcinogenesis; claim 17 limits claim 16 to probing proteins derived from the same tissue as used in the method of claim 1; claims 18 and 19 limits claim 1 by selecting the identified protein for use as a therapeutic target or diagnostic target, respectively; claim 20 reiterates the novel steps of claim 16 relative to claim 1; and claim 21 further limits claim 20 to include one of several validation steps. It is readily apparent that the limitations of claims 16-21 are taught by the combined teaching of Rapp and Chen, Reddy, *et al.*, and Gachon, *et al.* As outlined above, Rapp and Chen teaches the association of HPV E6 and HTLV-I tax with hDLG protein and mutational analysis in fibroblastic cell lines to discover correlation of the presence of either or both proteins with transformation. Rapp and Chen does not teach further using hDLG protein as probe for additional cellular carcinogenesis factors. Reddy, *et al.* teaches independent discovery of the association of HTLV-1 Tax with a cellular transcription factor variously referred to as ATF4 or CREB-2 using yeast two-hybrid systems with Tax as bait. Gachon, *et al.* teaches using CREB-2 as bait in a yeast two-hybrid system and the discovery of its direct interaction with CHOP—C/EBP-

homologous protein, a small bZIP factor expressed in response to metabolic stresses that binds to CAAT/enhancer consensus sites.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rapp and Chen by using a protein identified as interacting with at least two viral oncoproteins as probe for additional proteins involved in carcinogenesis as taught by Reddy, *et al.* and Gachon, *et al.*

The level of ordinary skill in the art is that of a senior post-doctoral fellow.

The skilled artisan would have been motivated to do so to further elucidate a pathway leading to cancerous states. There would have been a reasonable expectation of success, given the success of yeast two-hybrid methodology, as taught by Reddy, *et al.* and references cited therein. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

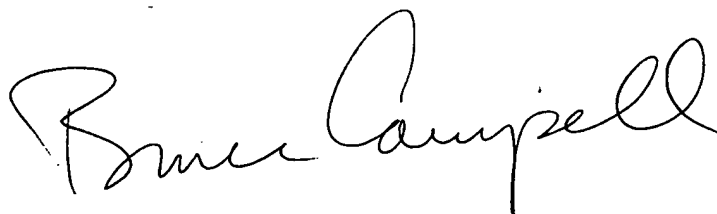
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
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